REMARKS

Favorable consideration of the subject application, in light of the following remarks pursuant to and consistent with 37 C.F.R. § 1.112, are respectfully requested.

Upon entry of the present amendment, Claims 101-132 and 135-138 will be pending in this application.

Applicants would first like to thank Examiner Gambel and SPE Paula Hutzell for the courtesy of granting Applicants' representatives interviews on September 13, 2001 and October 4, 2001. During the interviews, Examiner Gambel indicated that the claims would be allowable upon correction of the above-indicated minor informalities in the specification and claims. Support for new Claims 136-138 can be found in the specification at least at page 3, line 30 to page 4, line 2. No new matter has been added.

In order to comply with the duty of disclosure, Applicants note for the record that sequence errors in Figures 4 and 5 were discovered during the 146 action, and reflected in an expert report by Dr. John D. Stubbs, professor in the Biology Department at San Francisco State University. This expert report was previously submitted in an IDS in the present application, along with other documents from the 146 action.

Specifically, a sample identified as E. coli: W3110/pKCEAtrp207-1*Δ, pγCEAInt2 W3110p10$_2$ 1246-31 was produced as described in the specification at page 46, lines 16-23, and subsequently deposited at the American Type Culture Collection, 10801 University Boulevard, Manassas, Virginia 20110-2209 on March 15, 2000 and assigned deposit number PTA-1486 (see deposit receipt, attached hereto).[1]

During his study, Dr. Stubbs obtained DNA sequence data from W3110p10$_2$ 1246-31 which differs slightly from the sequence shown in Figure 4A and 5A of the Cabilly application as filed. The errors in the sequence are shown in the attached marked-up copies of Figures 4 and

[1]A second sample, designated W3110/p6$_2$ 1246-32, is a second doubly transformed *E. coli* strain which was prepared and deposited in the same manner as W3110/p10$_2$ 1246-31 and given designation PTA-1487 (pKCEAtrp207-1*, pγCEAInt2 W3110 p6$_2$ 1246-32).

5. The office has agreed that this sequence information is not necessary to support the present claims.

From the foregoing, further and favorable action in the form of a Notice of Allowance is respectfully requested and such action is earnestly solicited.

In the event that there are any questions relating to this amendment, or the application in general, it would be greatly appreciated if the Examiner would telephone the undersigned attorney at (703) 836-6620 concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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Date: October 4, 2001

Attachment to Amendment After Interference dated October 4, 2001

Marked-up Claims

101. (Amended) A process for producing an [Ig] immunoglobulin molecule or an immunologically functional [Ig] immunoglobulin fragment comprising at least the variable domains of the [Ig] immunoglobulin heavy and light chains, in a single host cell, comprising the steps of:

(i) transforming said single host cell with a first DNA sequence encoding at least the variable domain of the [Ig] immunoglobulin heavy chain and a second DNA sequence encoding at least the variable domain of the [Ig] immunoglobulin light chain, and

(ii) independently expressing said first DNA sequence and said second DNA sequence so that said [Ig] immunoglobulin heavy and light chains are produced as separate molecules in said transformed single host cell.

104. (Amended) A process according to claim [102]103 wherein the vector is a plasmid.

108. (Amended) A process according to claim 107 wherein the host cell is *E. coli* strain X1776 (ATCC No. 31537).

109. (Amended) A process according to claim 101 wherein the [Ig] immunoglobulin heavy and light chains are expressed in the host cell and secreted therefrom as an immunologically functional [Ig] immunoglobulin molecule or [Ig] immunoglobulin fragment.

110. (Amended) A process according to claim 101 wherein the [Ig] immunoglobulin heavy and light chains are produced in insoluble form and are solubilized and allowed to refold

in solution to form an immunologically functional [Ig] immunoglobulin molecule or [Ig] immunoglobulin fragment.

111. (Amended) A process according to claim 101 wherein the DNA sequences code for the complete [Ig] immunoglobulin heavy and light chains.

115. (Amended) A vector comprising a first DNA sequence encoding at least a variable domain of an [Ig] immunoglobulin heavy chain and a second DNA sequence encoding at least a variable domain of an [Ig] immunoglobulin light chain wherein said first DNA sequence and said second DNA sequence are located in said vector at different insertion sites.

118. (Amended) A transformed host cell comprising at least two vectors, at least one of said vectors comprising a DNA sequence encoding at least a variable domain of an [Ig] immunoglobulin heavy chain and at least another one of said vectors comprising a DNA sequence encoding at least the variable domain of an [Ig] immunoglobulin light chain.

121. (Amended) A method comprising

a) preparing a DNA sequence consisting essentially of DNA encoding an immunoglobulin [selected from the group] consisting of an immunoglobulin heavy chain [,] and light chain [, and] or Fab region, said immunoglobulin having specificity for a particular known antigen;

b) inserting the DNA sequence of step a) into a replicable expression vector operably linked to a suitable promoter;

c) transforming a prokaryotic or eukaryotic microbial host cell culture with the vector of step b);

d) culturing the host cell; and

e) recovering the immunoglobulin from the host cell culture, said immunoglobulin being capable of binding to a known antigen.

122. (Amended) The method of claim 121 wherein the heavy [or] and light chain are the heavy [or] and light chains of anti-CEA antibody.

127. (Amended) The method of claim 126 wherein the heavy chain [,] and light [chain,] chains or Fab region [is] are deposited within the cells as insoluble particles.

128. (Amended) The method of claim 127 wherein the heavy [or] and light chains are recovered from the particles by cell lysis followed by solubilization in denaturant.

129. (Amended) The method of claim 121 wherein the heavy [or] and light [chain is] chains are secreted into the medium.

130. (Amended) The method of claim 121 wherein the host cell is a gram negative bacterium and the heavy [or] and light [chain is] chains are secreted into the periplasmic space of the host cell bacterium.

132. (Amended) The insoluble particles of heavy chain [,] and light [chain,] chains or Fab region produced by the method of claim 127.